REMARKS

Claims 20-38 are currently pending in the application. Claim 19 was previously withdrawn, and claims 1-18 were previously canceled. Claims 20, 26-27 and 31 are amended herein to disclose that the therapeutic agent is associated with a pellet. Claims 20 and 26-27 also are amended to disclose that the pellets are sequentially implanted (Figs. 2A and 3A). Claim 31 also has been amended to disclose that the delivery chamber has an arcuate shape (Figs. 1 and 5). Claim 32 has been amended to disclose that the delivery chamber includes a port comprising resilient fingers. New independent claim 33 is based on claim 20 but includes the pellets as an element of the apparatus. New claims 34-38 depend from claim 33, and are based on claims 21, 22, 26, 27 and 30, respectively. No new matter is added.

INFORMATION DISCLOSURE STATEMENT

The action reports that a number of the foreign references listed on the PTO-1449 form dated April 7, 2005 in the parent application are missing from that file. Those references are filed herewith.

CLAIM OBJECTIONS

The Action objects to claims 31-32 as being of improper dependent form, on the reasoning that the phrase "means for receiving" is a second positive recitation of the delivery chamber of claim 20, and fails to further limit the subject matter of that claim.

Claim 31 has been amended to disclose that the delivery chamber has an arcuate shape, that is, it is bent, as shown in Figs. 1 and 5. Claim 32 has been amended to disclose that the delivery chamber includes a port comprising resilient fingers.

THE INVENTION

Applicants' invention is an apparatus for implanting a therapeutic agent within a tissue wall. It includes an elongate flexible body, a delivery chamber coupled to the distal end and having a space for carrying a plurality of sequentially positioned pellets comprising a therapeutic

agent, and a port for releasing the therapeutic agent. It also includes an actuator coupled to the delivery chamber and capable of sequentially driving pellets containing the therapeutic agent through the port. The distal end is adapted to penetrate a tissue wall so that the therapeutic agent can be delivered and implanted within the tissue wall.

The apparatus can also include a control mechanism coupled to the actuator, which provides control of the actuator, and a steering mechanism for turning the distal end of the apparatus, allowing the user to selectively guide the device through a body lumen. It can also include a lever-action handle coupled to the control mechanism.

The distal end can be dimensionally adapted to allow for transluminal delivery entry into the interior of a patient's heart. It can also include a plunger for driving the therapeutic agent from the delivery chamber, such as a threaded plunger for advancing into the delivery chamber in response to a rotating action, and a ratchet assembly for allowing delivery of the therapeutic agent in discrete amounts.

The delivery chamber can be substantially cylindrical, and adapted to receive and store the therapeutic agent in the form of pellets, for instance, minispheres or pellets having a pointed shape.

THE CITED ART

Lemelson (U.S. Pat. No. 4,578,061; "Lemelson")

U.S. Pat. No. 4,578,061 to Lemelson ("Lemelson") discloses several catheters for placing material within the body. The material is retained within a housing at the distal end of the catheter, which is inserted through a body lumen, such as a vein or artery, to a desired location, where the material is ejected from the device.

In one version of the device, shown in Figs. 1-3, a shaft 30 pushes piston 36 distally, driving a solid pill 37, viscous fluid or container for medication out of the distal tip of the device

and into "...a body duct such as an artery, the intestine, throat or other body duct." (column 2, lines 59-61).

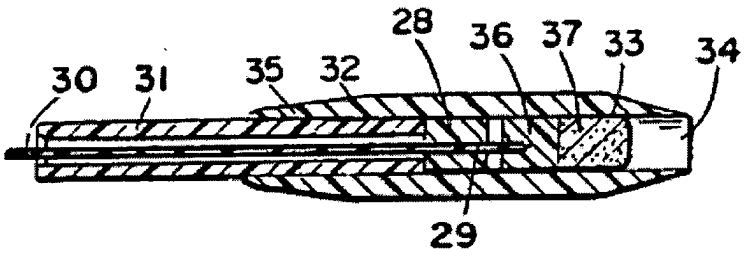

FIG. 1

In a second version of the device (Fig. 4), the actuator 30 engages a wedge-shaped piston 49P that pushes the solid pill or material 48B out the side of the device. The devices are said to cause the pill 37 to "...protrude[e] from the end ... or to eject it completely so that it lies against the tissue adjacent the end of the catheter." (column 3, line 65-68).

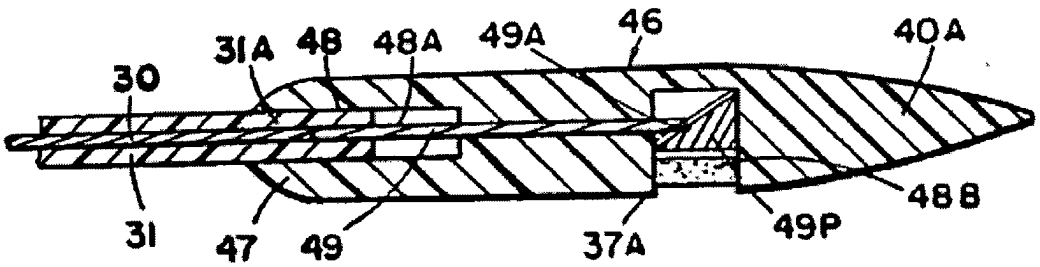

FIG.4

A third version (Figs. 5-6) has a first piston 86 which advances a hypodermic needle 94 out from the side of the device, and a second piston 90 which ejects a fluid out of the needle and into the tissue. "When the head 81 is at an operative location within a body duct such as a vein or artery, needle 94 may be caused to move forward through curved bore 84 to project its sharp end outwardly from the sidewall of head 81 so as to penetrate tissue of the body duct in which the head 81 is disposed and/or an organ or other object aligned therewith." (column 8, lines 58-64).

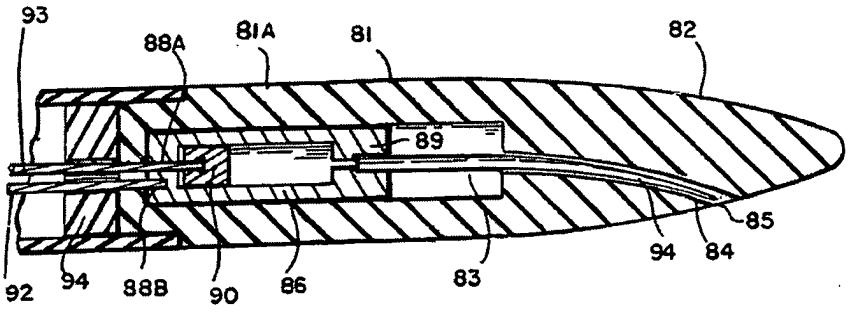

FIG.6

Leschinsky *et al.* (U.S. Pat. No. 5,873,499; "Leschinsky")

U.S. Pat. No. 5,873,499 to Leschinsky *et al.* ("Leschinsky") discloses a dispensing gun for dispensing a viscous fluid from a releasable dispenser, such as in a caulking gun.

THE REJECTIONS

Claim Rejections Under 35 U.S.C. § 102

Reconsideration is requested of the rejection of claims 20-26, 29 and 31-32 as anticipated by Lemelson. Lemelson '061 does not disclose a device adapted to hold a plurality of pellets containing a therapeutic substance and then sequentially implant one or more of the pellets in tissue. The Lemelson devices dispense either a single solid pill from the distal tip or the side of the device "to lie against tissue". Lemelson does not disclose or even contemplate the dispensing of multiple pellets. Rather, after the pill is delivered, the catheter is to be removed from the patient, sterilized, and reloaded with a new pill. (column 4, lines 10-17).

To the extent that Lemelson, in Figs. 5-6, discloses a device for injecting into tissue (as compared to delivery to lie against tissue) the delivery is of a fluid delivered by fluid pressure, not as a plurality of sequentially dispensed pellets.

Claim Rejections Under 35 U.S.C. § 103

Reconsideration is requested of the rejection of claims 27-28 and 30 as defining subject matter that would have been obvious to one of ordinary skill in the art over Lemelson and

Leschinsky. Leschinsky discloses a pressure fluid dispensing gun, such as a caulking gun, in which a fluid containing dispensing cartridge decouples when a specific high pressure is reached to prevent the dispenser from falling to the ground (column 1, lines 1-50). Wholly apart from the improper hindsight combination of a medical delivery device (Lemelson) and a caulking gun, neither of these references discloses the claimed arrangement of a device that can sequentially implant a plurality of pellets into tissue. Lemelson does not disclose a device that can implant a plurality of pellets sequentially, and Leschinsky does not disclose a device that can implant solid material at all. Where neither reference discloses such a device, their combination cannot render the device obvious.

The rejections should be withdrawn.

Applicant submits that all of the claims are now in condition for allowance, which action is requested. Please apply any charges or credits to Deposit Account No. 50-1721.

Respectfully submitted,

Joyce C. Hersh
Reg. No. 42,890
Attorney for Applicant
KIRKPATRICK & LOCKHART
NICHOLSON GRAHAM LLP
75 State Street
Boston, MA 02109-1808
Tel: 617-261-3100
Fax: 617-261-3175

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